DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: InFUSE Bone Graft/LT-CAGE
Lumbar Tapered Fusion Device
Docket Nos.: 2003E-0243 and 2003E-0244

MAR 1 3 2007

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the applications for patent term extension for U.S. Patent Nos. 5,782,919 and 5,984,967 filed by SDGI Holdings, Inc., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the applications and have determined the regulatory review period for InFUSE Bone Graft/LT-CAGE Lumbar Tapered Fusion Device, the medical device claimed by the patents.

The total length of the regulatory review period for InFUSE Bone Graft/LT-CAGE Lumbar Tapered Fusion Device is 2,052 days. Of this time, 1,515 days occurred during the testing phase and 537 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act involving this device became effective: November 20, 1996.

   FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act for human tests to begin became effective on November 20, 1996.

2. The date the application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act: January 12, 2001.

   FDA has verified the applicant's claim that the premarket approval application (PMA) for InFUSE Bone Graft/LT-CAGE Lumbar Tapered Fusion Device (PMA P000058) was initially submitted on January 12, 2001.

3. The date the application was approved: July 2, 2002.

   FDA has verified the applicant's claim that PMA P000058 was approved on July 2, 2002.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Christopher A. Brown, Esq.
Woodward, Emhardt, Naughton, Moriarty & McNett
Bank One Center, Tower
111 Monument Circle, Suite 3700
Indianapolis, IN 46204-5137